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OFFICE OF WATER REGULATIONS
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Prepared by

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Under the 1977 Clean Water Act, Congress mandated the U.S. Environmental Protection Agency to develop ambient water quality criteria for 129 priority Pollutants. These criteria were published in 1980. Under Section 304(a)(1) of the Clean Water Act as amended in 1987, the U.S. EPA is mandated to re-evaluate and update these criteria every five jears. These addenda represent an updated literature search current as of 1988, plus additional information form Agency files and Program Offices. This addendum is to update the existing Ambient Water Quality Criteria Document for Acrylonitrile.

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PREFACE

Under the 1977 Clean Water Act, Congress mandated the U.S. Environmental Protection Agency to develop ambient water quality criteria for 129 priority pollutants. These criteria were published in 1980. Under Section 304(a)(1) of the Clean Water Act as amended in 1987, the U.S. EPA is mandated to re-evaluate and update these criteria every five years. These addenda represent an updated literature search current as of 1988, plus additional information from Agency files and Program Offices. The first draft of this addendum was prepared by Syracuse Research Corporation under contract no. 68-C8-0004.

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LIST OF ABBREVIATIONS

BCF	Bioconcentration factor
CNS	Central nervous system
CRAVE	Carcinogen Risk Assessment Verification Endeavor
LOAEL	Lowest-observed-adverse-effect level
NOAEL	No-observed-adverse-effect level
ppm	Parts per million
RfD	Reference Dose
RQ	Reportable quantity
TLV	Threshold limit value

INTRODUCTION

Under Section 304(a)(1) of the Clean Water Act of 1977 as amended in 1987, the U.S. EPA is required to publish criteria for water quality accurately reflecting the latest scientific knowledge regarding the effects on health and welfare that may occur from the presence of pollutants in any body of water, including groundwater. In accordance with the 1977 act, Ambient Water Quality Criteria Documents (AWQCDs) were developed in 1980 for 65 toxic pollutants or classes of pollutants listed under Section 307(a)(1).

These addenda are intended to serve as an update of the original AWQCDs. The addenda provide the Agency with the latest scientific assessments of potential health hazards associated with these pollutants and serve as guidelines for modifying the current (1980) AWQCDs.

The human health criteria in these addenda are based on Agency verified risk assessment values when available. These values consist of reference doses (RfD) for those chemicals believed to be systemic toxicants (i.e., do not induce cancer) and cancer risk factors for those thought likely to cause cancer in humans. The verification process consists of a review and consensus of risk assessment values provided by an Agency workgroup consisting of scientists from each of the major Agency offices. Assessments for noncarcinogens are verified by the RfD workgroup and those for carcinogens are verified by the Carcinogen Risk Assessment Verification Endeavor (CRAVE) workgroup. If such values are not available, the criteria are based on the most recent Agency health assessment. In the absence of any appropriate Agency value, RfD values or cancer risk factors are derived by current Agency methods if adequate new data are available, and criteria are recommended based on the proposed RfD or risk factor.

The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD is derived by dividing a NOAEL or LOAEL for subchronic or chronic exposure by standard uncertainty factor(s) times an additional uncertainty factor:

$$RfD = \frac{\text{NOAEL or LOAEL}}{UF(s) \times UF}$$

The standard uncertainty factors are applied to reflect the various types of data used to estimate RfDs. An uncertainty factor of 10 is used to account for variations in human sensitivity when extrapolating from valid human studies involving long-term exposure of average, healthy subjects. An additional 10-fold factor is used for each of the following: to extrapolate from long-term animal studies to the case of humans, to extrapolate from subchronic animal studies to chronic exposure, and to extrapolate from a LOAEL to a NOAEL. An additional uncertainty factor of >0-10 may be applied to reflect professional assessment of the uncertainties of the study and data base not explicitly addressed by the standard uncertainty factors (i.e., completeness of the overall data base). The default value for the additional uncertainty factor is 1.

In assessing the carcinogenic potential of a chemical, the U.S. EPA classifies the chemical into one of the following groups according to the degree of evidence in epidemiological studies and animal studies: Group A - Human Carcinogen; Group B - Probable Human Carcinogen [limited evidence in humans with or without sufficient evidence in animals (Group B1) or inadequate evidence in humans with sufficient evidence in animals (Group B2)]; Group C - Possible Human Carcinogen (limited evidence of carcinogenicity in animals in the absence of human data); Group D - Not Classifiable as to

Human Carcinogenicity (inadequate or no evidence); Group E - Evidence of Noncarcinogenicity for Humans. Quantitative carcinogenic risk assessments are performed for chemicals in Groups A and B, and on a case-by-case basis for chemicals in Group C. Upper-bound cancer unit risks (slope values) are estimated through the use of mathematical extrapolation models. Most commonly for animal data, the linearized multistage model with a 95% upper confidence limit is used to provide a low-dose estimate of cancer risk. The cancer risk is characterized as an upper-limit estimate (i.e., the true risk to humans, while not identifiable, is not likely to exceed the upper-limit estimate and in fact may be lower). Alternative risk models to the multistage model, such as the one-hit, Weibull, Logit or Probit model, are available and may be used when the evidence indicates that they may be more appropriate. In the absence of such evidence, the Agency recommends the linearized multistage model to provide consistency of approach and an upper-bound on the potential carcinogenic risk. In the case where human data are used for quantitative risk assessment, an upper-bound estimate rather than a 95% upper-bound estimate is used when low-dose linearity is assumed.

In the development of this Addendum to the AWQCD on acrylonitrile, recent Agency assessments have been consulted. A computerized literature search was conducted to cover studies published more recently than the latest Agency assessment (i.e., published in 1987 to 1988). New key studies have been evaluated.

REVIEW OF NEW DATA

Toxicologic/Carcinogenic Effects

Several animal studies regarding the carcinogenicity of acrylonitrile have been published subsequent to U.S. EPA (1980), and were recently evaluated in U.S. EPA (1985, 1987a,b). Two studies performed by Biodynamics, Inc. (1980a,b) showed that acrylonitrile increases the incidence of brain tumors in rats.

In the first study by Biodynamics, Inc. (1980a), Sprague-Dawley rats (100/sex/group) were given acrylonitrile (0, 1 or 100 ppm) in their drinking water for 19 (females) or 22 (males) months. Interim necropsies were performed at 6, 12 and 18 months on 10 rats/sex/group. The experiment was terminated earlier than expected because of low survival. In the high-dose groups, there was a slight but consistent decrease in both body weight and water intake, and a statistically significant ($p<0.05$) increased incidence in astrocytomas of the brain and spinal cord, carcinomas of the Zymbal gland, and squamous cell carcinomas and papillomas of the forestomach in males and females.

In a more extensive study (Biodynamics, Inc., 1980b), F344 rats (100/sex/group) were given acrylonitrile in their drinking water at dose levels of 1, 3, 10, 30 or 100 ppm (0.11, 0.25, 0.81, 2.49, 8.15 mg/kg/day) for 23 months (males) or 26 months (females). There were 200 rats/sex in the control group. Interim necropsies were performed at 6, 12 and 18 months on 10 rats/sex/group and on 20 rats/sex from the control group. Male and female rats that received $\geq$3 ppm acrylonitrile had increased incidences of astrocytomas of the brain and spinal cord and carcinomas of the Zymbal gland. This incidence was dose dependent and statistically significant ($p<0.05$). Females that received 100 ppm had an increased incidence of

mammary gland carcinomas. The actual dose-response data for these experiments are reported in U.S. EPA (1987b) and provided in Table 1.

Quast et al. (1980) administered acrylonitrile in drinking water at dose levels of 35, 100 and 300 ppm to 48 Sprague-Dawley rats/sex for 2 years. A statistically significant increase in tumors was observed in the CNS (astrocytomas), Zymbal gland, stomach, tongue and small intestine for both sexes, and in the mammary gland of female rats. In general, the increase was dose-dependent.

In a more recent study (Bigner et al., 1986) specific types of brain tumors were observed in F344 rats (50/sex/group) that received 0, 100 or 500 ppm of acrylonitrile in their drinking water for 18 months. An additional group of 300 rats of both sexes received 500 ppm. Tumor incidences for the initial groups of 50 were not described clearly. In the rats treated at 500 ppm, 215 brains were examined and 49 tumors were found. These tumors were examined histologically and found to be densely cellular, with intermingling cytoplasmic processes and occasional areas of focal necrosis. The cells showed no glial filaments, secretory granules or specialized cell contacts. This study supports the findings from the studies described above, because of the lack of dose-response data, it is inappropriate for determining quantitative risks.

Human data regarding the carcinogenicity of acrylonitrile, useful in assigning the weight of evidence classification, are also available. O'Berg (1979), originally cited in U.S. EPA (1980) and later expanded (O'Berg, 1980), found 25 cases of cancer among 1345 male Du Pont textile workers exposed to 5-20 ppm (mean of 15 ppm) acrylonitrile. Exposure occurred over a 16-year period (1950-1966) with a minimum 10-year follow-up. Of the 25 cases (20.5 expected) of cancer, 8 were of the respiratory system (4

expected). All the cancers occurred in workers (1128 employees) with at least 6 months of exposure. The increased incidence of respiratory cancer was statistically significant after a correction for smoking (5 observed vs. 1.6 expected).

A more recent analysis of a cohort of 1083 Du Pont textile male workers was reported by Chen et al. (1987). Exposure period was from 1944-1970 and the folow-up for mortality was through 1981 and through 1983 for cancer incidence. In total, 37 cancer cases occurred as compared with 36.5 expected. Among these 37 cases, 21 cancer deaths were reported, which was fewer than expected based on either Du Pont or U.S. rates. No significant excesses were seen by primary site, with the possible exception of an increase in prostate cancer (5 observed vs. 1.9 expected). Of these, 4 occurred among wage employees during the 1975-1983 period, compared with 0.9 expected.

Although there appears to be some increased incidence in the occurrence of prostate cancer, this study had several deficiencies that make it inadequate for cancer assessment. No quantitative exposure data was available between 1944 and 1970. Exposures were classified into three categories (high, medium and low). It is entirely possible, therefore, that very little actual exposure occurred for some members of the cohort. There was significantly less mortality in both wage and salaried employees. There was also a significant deficit in the number of cancer deaths in salaried employees (3 observed vs. 12.3 expected U.S. male). Finally, the distribution of cancer cases and the fact that only prostate cancers were significantly elevated in this cohort may indicate that a rather old group of persons were studied, also latency by cancer site was not reported for this cohort.

In addition to the Chen et al. (1987) study, several other studies have reported nonsignificant increases in deaths from cancer following occupational exposure to acrylonitrile. These studies are discussed in detail in U.S. EPA (1987b). Deficiencies in the design or methodology of these studies as well as that of Chen et al. (1987) render them inadequate to assess the carcinogenic effects of exposure to acrylonitrile.

Another study (Monson, 1977) that was initially reviewed in U.S. EPA (1980), was published later (Delzell and Monson, 1982) and has been reviewed by U.S. EPA (1987b). A significant increase in lung cancer (9 observed vs. 5.2 expected) was found in 327 male rubber workers exposed to acrylonitrile for 4-26 years. U.S. EPA (1987b) also reviewed two other epidemiological studies (Thiess et al., 1980; Werner and Carter, 1981) linking acrylonitrile to increased incidences of lung or stomach cancer in humans, but these studies lacked details regarding the smoking history of workers and quantitation of exposure levels.

Acrylonitrile has been classified as Group B1 based on increased incidence of lung cancer in humans exposed by inhalation, and in two rat strains exposed by various routes (U.S. EPA, 1987b).

Bioconcentration Factor (BCF)

Pertinent new information concerning the bioconcentration factor for acrylonitrile is currently undergoing Agency review. The BCF value of 30 determined in U.S. EPA (1980) will be used until this review is complete.

QUANTIFICATION OF EFFECTS

The 1980 ambient water quality criteria (U.S. EPA, 1980) were based on a study by Quast et al. (1980), which showed that Sprague-Dawley rats (48/sex/group) that received acrylonitrile in their drinking water (0, 35, 100 or 300 ppm) for 2 years had a statistically significant increase in carcinomas of the brain, spinal cord, Zymbal gland, stomach, tongue and small intestine. In addition, the females had increased incidences of tumors in the mammary gland.

The 1980 ambient water quality criteria (U.S. EPA, 1980) for acrylonitrile corresponding to lifetime increased cancer risk levels of 10^{-7}, 10^{-6} and 10^{-5} were 0.006, 0.058 and 0.58 µg/ℓ, respectively, for consumption of water and fish and shellfish. For consumption of fish and shellfish only, the respective criteria were 0.065, 0.65 and 6.5 µg/ℓ. These criteria were based on a slope factor of 0.522 $(mg/kg/day)^{-1}$ and a BCF of 30. The calculations assumed a human body weight of 70 kg and a daily intake of 2 ℓ of water. The slope factor was derived from dose-response data for the induction of astrocytomas in the CNS of female rats administered acrylonitrile in the drinking water for 2 years in the study by Quast et al. (1980).

The U.S. EPA (1987b) has reassessed the available oral data and derived a new slope factor that should be used as the basis for new ambient water quality criteria. This slope factor is based on the two Biodynamics, Inc. (1980a,b) studies and the Quast et al. (1980) study, which provided dose-response data for combined incidences of brain and spinal cord astrocytomas, Zymbal gland carcinomas and stomach papillomas in male rats given acrylonitrile in the drinking water. The combined tumor incidences from these three studies are presented in Table 1.

TABLE 1

Route: Drinking Water

Species/Strain	Tumor Type	Dose Administered		Human Equivalent (mg/kg/day)	Tumor Incidence	Reference
		ppm	mg/kg/day			
Rats/Spartan Sprague-Dawley, males	brain and spinal cord astrocytomas, Zymbal gland carcinomas and stomach papillomas/carcinomas	0	0.00	0.00	6/100	Biodynamics, 1980a
		1	0.09	0.02	6/98	
		100	7.98	1.36	36/98	
Rats/Fischer 344, males	brain and spinal cord astrocytomas, Zymbal gland carcinomas and stomach papillomas/carcinomas	0	0.00	0.00	5/200	Biodynamics, 1980b
		1	0.11	0.02	4/100	
		3	0.25	0.04	5/100	
		10	0.81	0.14	7/100	
		30	2.49	0.43	20/100	
		100	8.15	1.39	34/100	
Rats/Sprague-Dawley, males	brain and spinal cord astrocytomas, Zymbal gland carcinomas and stomach papillomas/carcinomas	0	0.00	0.00	4/80	Quast et al., 1980
		35	3.42	0.58	18/47	
		100	8.53	1.46	36/48	
		300	21.18	3.62	45/48	

The slope factors from these three studies are 4.0×10^{-1}, 4.0×10^{-1} and 9.9×10^{-1}, respectively, derived using the linearized multistage extrapolation method. The geometric mean of these three slope factors resulted in a verified slope factor of 0.54 $(mg/kg/day)^{-1}$.

Using the verified slope factor of 0.54 $(mg/kg/day)^{-1}$ and assuming a 70 kg body weight and a daily intake of 2 ℓ of water and 6.5 g of fish and shellfish with a BCF of 30, the criteria for acrylonitrile in ambient water are as follows:

Exposure Assumptions (per day)	Risk Levels and Corresponding Criteria (µg/ℓ)				
	0	10^{-7}	10^{-6}	10^{-5}	10^{-4}
2 ℓ of drinking water and consumption of 6.5 g of fish and shellfish	0	0.0059	0.059	0.59	5.9
Consumption of fish and shellfish only	0	0.066	0.66	6.6	66

The verified slope factor (U.S. EPA, 1987b) and the new criteria based on that factor are similar to the slope factor and criteria derived in the 1980 AWQCD (U.S. EPA, 1980).

EXISTING STANDARDS AND CRITERIA

The verified oral slope factor for acrylonitrile is 0.54 $(mg/kg/day)^{-1}$ (see previous section), and the cancer unit risk for exposure to 1 µg/ℓ of drinking water is 1.5×10^{-5} $(\mu g/\ell)^{-1}$ (U.S. EPA, 1987b).

The verified inhalation slope factor cited in IRIS (U.S. EPA, 1987b) is 0.24 $(mg/kg/day)^{-1}$ based on a study of human respiratory cancer (O'Berg, 1980), and the corresponding cancer unit risk factor for exposure to 1 $\mu g/m^3$ of air is 8.6×10^{-5} $(\mu g/m^3)^{-1}$.

The ACGIH (1987) TLV-TWA for acrylonitrile is 2 ppm, or 4.5 mg/m^3. It is classified by ACGIH (1987) using the OSHA cancer classification scheme as a suspected human carcinogen (A2). According to ACGIH (1986), the current OSHA standard is 2 ppm for an 8-hour TWA and the ceiling limit is 10 ppm.

An RQ of 10 pounds has been proposed for acrylonitrile, based on carcinogenicity (U.S. EPA, 1988).

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